

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt. 1:13-md-02419-RWZ

THIS DOCUMENT RELATES TO:

Dkt. No. 1661

**PLAINTIFFS' STEERING COMMITTEE'S OPPOSITION
TO LIBERTY INDUSTRIES, INC.'S MOTION TO STRIKE THE
AMENDED DECLARATION OF PHILIP J. AUSTIN, PH.D.**

The Plaintiffs' Steering Committee ("PSC") hereby opposes Liberty Industries, Inc.'s Motion to Strike the Amended Declaration of Philip J. Austin, Ph.D. (the "Motion to Strike").¹

I. OVERVIEW

This Court has gone to great lengths to promptly adjudicate the Motion for Summary Judgment filed by Liberty Industries, Inc. ("Liberty"). After considering all of the arguments and deciding that genuine questions of material fact exist, this Court denied Liberty's summary judgment motion.² Liberty has now filed a motion for reconsideration,³ which the PSC opposed.⁴ Oral argument was heard regarding the motion for reconsideration at the January 14, 2015 status conference.⁵ After the status conference the PSC filed an Amended Declaration of Philip J. Austin, Ph.D. (the "Amended Declaration").⁶ The only change in the Amended

¹ Dkt. 1661, Liberty's motion to strike the amended declaration of Philip J. Austin, Ph.D. All docket numbers identified herein refer to the MDL docket, 13-md-2419-RWZ.

² Dkt. 1613, decision denying Liberty's motion for summary judgment.

³ Dkt. 1619, Liberty's motion for reconsideration of denial of Liberty's motion for summary judgment.

⁴ Dkt. 1610, PSC's opposition to Liberty's motion for summary judgment.

⁵ January 14, 2015 Status Conference Transcript, pp. 15-22.

⁶ Dkt. 1651, PSC's notice of filing of amended declaration of Philip J. Austin, Ph.D.

Declaration from the one filed originally was to add the words “signed under the pains and penalties of perjury” before Dr. Austin’s signature. The motion at issue here requests that this Court strike the Amended Declaration.

Although the PSC feels strongly that a genuine question of material fact exists without Dr. Austin’s declaration and that the Court has the authority to consider Dr. Austin’s declaration as it was originally filed, the PSC filed the Amended Declaration in order to dispel any question about Dr. Austin’s opinion and any technical issue with the original declaration.

Liberty now claims that the PSC filed the Amended Declaration, “without any authority from the Court.”⁷ During the January 14 status conference, Ms. Johnson stated that the PSC would file a corrected copy of the Austin Declaration.⁸ Liberty did not object to this, nor did the Court address the issue. Now that the PSC corrected any procedural defect in the expert declaration, Liberty moves to exclude the document on other meritless grounds. Essentially, Liberty has filed a second motion for reconsideration before its first motion for reconsideration has even been denied. The grounds set forth in Liberty’s Motion to Strike are meritless.

II. LEGAL STANDARD

A motion to strike an expert report is strongly disfavored, and the decision to do so rests within the discretion of the court.⁹ The proponent of a motion to strike an expert report bears an exceptional burden.¹⁰ “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking

⁷ Dkt. 1661, Liberty’s motion to strike the amended declaration of Philip J. Austin, Ph.D. (“Motion to Strike”).

⁸ January 14, 2015 Status Conference Transcript, p. 20, lines 13-18.

⁹ See *Barnes v. D.C.*, 289 F.R.D. 1, 6 (D.D.C. 2012) (citing *Judicial Watch, Inc. v. Dep’t of Commerce*, 224 F.R.D. 261, 263 (D.D.C. 2004); 12 MOORE’S FEDERAL PRACTICE, Civil § 12.37 (2006)).

¹⁰ *Id.* (citing *Judicial Watch*, 289 F.R.D. at 264).

shaky but admissible evidence.”¹¹ Even “[w]hen the factual underpinning of an expert opinion is weak, it is a matter affecting the weight and credibility of the testimony and a question to be resolved by the jury.”¹²

III. ARGUMENT

A. Dr. Austin’s declaration is based on his personal knowledge and observations.

Dr. Austin personally inspected the NECC facility and the Liberty cleanrooms in December of 2012 as part of a three day inspection organized before NECC filed for bankruptcy.¹³ Liberty’s claim that Dr. Austin lacks personal knowledge sufficient to support his declaration is false.

Liberty devotes an entire section in its Motion for Summary Judgment arguing that the cleanrooms at NECC were altered since Liberty designed and constructed them. Dr. Austin opines, based on his personal observation of the ceiling, that there have been no alterations since their construction that could account for the ceiling gaps observed and that the gaps result not from subsequent modification, but as a result of original design and installation.¹⁴ Dr. Austin’s personal observations and his professional experience is an adequate basis for his opinion that the gaps are the result of design and building choices that Liberty made during the construction

¹¹ *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011). *See also Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (admitting testimony notwithstanding a lack of peer reviewed publications because the opinion rested upon good grounds generally and should be tested by the “adversarial process”).

¹² *Newell Puerto Rico, Ltd. v. Rubbermaid Inc.*, 20 F.3d 15, 21 (1st Cir. 1994); *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011); *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998).

¹³ Amended Declaration at ¶¶33-35.

¹⁴ “Based on the size and appearance of some of these gaps in the ceiling, I believe that these defects were present as a result of the initial installation of the ceiling system. There was no observable evidence to suggest that any modifications to the ceiling had been made in these areas. Furthermore, the design of the ceiling would have made it extremely difficult for any such modifications that would have resulted in the formation of these gaps to be made without a complete replacement of the ceiling.” Amended Declaration at ¶ 43.

and installation of the cleanroom, and that Liberty's faulty design and installation is a cause of Plaintiffs' injuries. The ceiling gaps observed by Dr. Austin are not speculative nor is the opinion Dr. Austin proffers as a result of his personal observations. Liberty never offers any evidence to support the argument that subsequent modifications to the cleanroom's ceilings (if any) caused the ceiling gaps Dr. Austin observed. And, even if it did, this would merely create a disputed question of fact that cannot be determined at summary judgment, as the Court has already concluded.¹⁵

B. The PSC has provided evidentiary proof that the contaminated drugs were compounded in the 2006 cleanroom.

As was stated in the PSC's Opposition Brief to Liberty's Motions for Summary Judgment, the contaminated drugs were compounded exclusively in the 2006 cleanroom.¹⁶ The PSC provided documentary evidence that the drugs in question were compounded in the 2006 cleanroom.¹⁷ Liberty's argument that Dr. Austin is speculating as to which room the contaminated MPA was compounded ignores this evidence.¹⁸ In their own motion for summary judgment and accompanying affidavit Liberty conceded that all evidence indicates the drugs were compounded in the 2006 cleanroom. In their Statement of Undisputed Material Facts Unifirst cites its own expert's affidavit and its own expert's inspection of the facility in July 2014 as indicating that MPA ingredients were found in the 2006 cleanroom and that "Liberty has not received any indication that the contaminated MPA was compounded in the 2005 or 2008 Cleanrooms."¹⁹ This issue has been

¹⁵ " . . . in light of the declaration of plaintiff's expert highlighting substantial alleged design flaws . . . genuine issues of fact remain for the jury to decide." Dkt. 1613, p. 6.

¹⁶ Dkt. 1610, PSC's opposition to Liberty's motion for summary judgment, p. 7, citing Sobol Dec. Ex. 15 (filed under seal).

¹⁷ *Id.*

¹⁸ Dkt. 1661, Liberty's motion to strike, p. 2, ¶2.

¹⁹ Dkt. 1472, Liberty's memorandum in support of summary judgment, at 4-5, citing the Affidavit of Jeffrey Erickson, at ¶ 13-14.

resolved, but, at minimum, it presents a disputed question of fact for a jury to decide, not a basis for striking Dr. Austin's Amended Declaration.

C. Liberty's admits it understood the NECC cleanrooms were intended to be used to compound drugs.

Liberty's own employees have established, through testimony at deposition, that Liberty knew and understood the NECC cleanrooms were meant to be used for the sterile compounding of drugs. Liberty's claim that Dr. Austin's declaration should be stricken because there is no such evidence is plainly incorrect.²⁰

Mr. Erickson, the Liberty project "engineer" who oversaw the design and construction of the NECC cleanrooms, admits that he understood the 2006 cleanroom was going to be used for compounding drugs.

Q. And at the time when you were providing the design services . . . did you have any understanding as to the purpose for which the clean room was going to be put to use?

...

A. Other than compounding as a general statement.²¹

Further, USP <797> sets forth requirements for sterile compounding. The purpose of USP <797> is quite clear:

The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins . . .²²

²⁰ Motion to Strike, p. 2.

²¹ Ex. 2 to Declaration of Thomas M. Sobol filed herewith, Erickson Dep. Trans. 141:20-142:2.

²² Sobol Dec. Ex. 1, USP-NF General Chapter <797> Pharmaceutical Compounding-Sterile Preparations, USP 35/NF 30 (2012).

Mr. Erickson testified that he is familiar with USP <797>.²³ Liberty marketed its cleanrooms – the same cleanrooms built at NECC– as being USP <797> compliant.²⁴ Liberty designed and built the 1996 NECC cleanroom under the USP <797> standards as an ISO 6 cleanroom.²⁵ The very title of USP <797> “*Pharmaceutical Compounding – Sterile Preparations*” belies any claim by Liberty that it did not understand that the purpose of the room was the sterile compounding of drugs. At best there is a question of fact presented by Liberty’s claim of ignorance which underscores the appropriateness of the Court’s decision to deny summary judgment.

D. Dr. Austin’s declaration expresses his own professional opinion.

Dr. Austin is more than qualified to render opinions related to the cleanrooms. Dr. Austin *files* has decades of specialized relevant experience related to the design and construction of cleanrooms, and holds an Aerospace Engineering Bachelor, Master, and Doctorate degrees from the University of Michigan.²⁶ While Dr. Austin’s father is a world renowned expert on the subject of cleanroom design and construction, Liberty ignores that Dr. Austin personally inspected the NECC facility with his father and others. Dr. Austin submitted his declaration under penalty of perjury stating that it is “based on my personal knowledge, except when stated otherwise, and if called upon to testify, I am competent to testify to the matters contained herein.”²⁷ Dr. Austin’s use of plural subjects in some sentences of his report is appropriate and does not somehow indicate that he does did not make personal observations concerning the

²³ Sobol Dec. Ex. 2, Erickson Dep. Trans. 46:8-9; See also Kaiser Dep. Trans. 23:10-15.

²⁴ Sobol Dec. Ex. 3, Kaiser Dep. Trans 25:16-19; 26:21-24.

²⁵ Sobol Dec. Ex. 2, Erickson Dep. Trans. 69:3-9.

²⁶ Amended Declaration, p. 1, ¶1, Professional Background.

²⁷ Amended Declaration, p. 21, ¶54.

subject of his opinion or that his opinions are not his own or are somehow dependent on his father's expertise rather than his own.

E. Plaintiffs need only prove that Liberty's breach was a contributing factor in the outbreak.

Plaintiffs are not obligated to present facts that would permit a reasonable jury to conclude that Liberty was the sole cause of the outbreak, nor are they required to prove with 100% certainty the definitive route of causation. Plaintiffs only need show that Liberty's failures more likely than not contributed to the outbreak. Liberty's argument that the Amended Declaration must be stricken because Dr. Austin states that the cause of the fungal meningitis outbreak will not likely be definitively identified is misguided.²⁸ Liberty seeks to rehash the causation argument already made by Liberty and rejected by the Court.²⁹ Dr. Austin's opinion that Liberty's defective design and construction of the NECC cleanroom was a proximate cause of the fungal contamination is not somehow inadmissible simply because he has not opined that Liberty is the sole potential cause of the contamination. It is well-established that when there are two or more contributing causes for injuries sustained, the causation requirement is satisfied for each defendant if each "owe[d] concurrent duties to the injured party, [then] each may be liable for breach of their respective duty."³⁰ As such, Liberty's conduct need not be the only cause of injuries in order for it to be liable to the victims of this outbreak.³¹

²⁸ Dkt. 1661, Liberty's motion to strike.

²⁹ Dkt. 1472, Liberty's memorandum in support of summary judgment, at 14.

³⁰ *National R.R. Passenger Corp. v. Everton by Everton*, 655 N.E.2d 360, 366 (Ind. Ct. App. 1995).

³¹ *Id.*; See also *Ingersoll-Rand Corp. v. Scott*, 557 N.E.2d 679, 684 (Ind. Ct. App. 1990) (acts of negligence need not be the sole proximate cause of the injury in order for liability to arise.).

IV. CONCLUSION

Liberty Industries, Inc.'s entreating that it lacks resources and insurance to defend itself against the claims of the Plaintiffs in this mass tort has imposed the burden on the PSC and the Court to address Liberty's defenses in an expedited manner and before adequate discovery has been completed. Having received a ruling not to its liking, Liberty now implores the Court to change its mind, continuing its pattern of seeking extraordinary, premature relief. The PSC understands Liberty's conundrum, but balanced against Liberty's financial difficulties are the near 1000 confirmed injured and dead who suffered due to Liberty's malfeasance. This Court's ruling that genuine questions of material fact exist was correct when made, and remains accurate today. Liberty's attempts to prematurely force a different result by striking the Amended Declaration should be denied.³²

Dated: January 26, 2015

Respectfully submitted,

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³² Dkt. 1613, decision denying Liberty's motion for summary judgment.

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: January 26, 2015

/s/ Thomas M. Sobol
Thomas M. Sobol